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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,071	06/22/2006	Shigenori Tanaka	Q95625	4850

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EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
02/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/584,071	TANAKA ET AL.	
	Examiner	Art Unit	
	Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 14-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/22/2006 & 11/20/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Response and amendment filed 07 December 2009 to Office Action mailed 08 September 2009 is acknowledged and entered.

2. Also acknowledged and entered is the Statement of Substance of Interview filed 07 December 2009.

Claims Status

3. Claims 1-23 are pending.

4. Claims 1-2, 4, 8, 10-11, 1316,-17, 19 and 22 have currently been amended.

Election/Restriction

5. Election without traverse of Claims 11-12 for further prosecution filed 07 December 2009 is acknowledged and entered. Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, Claims 1-10 and 13-23 are withdrawn from further consideration as being directed to a non-elected invention. See 37 C.F.R. §1.142(b) and M.P.E.P. §821.03.

6. Claims 11-12 are examined on merits.

Rejoinder

7. Upon further consideration that method Claims 11-12 require steps described in Claim 10 and further that Claim 13 employs the methods of Claims 11-12 to detect an endotoxin-related disease; Claims 10 and 13 previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined with the elected Claims 11-12 of Group "C" invention (See Office Action mailed 09/09/2009 and further the Office Action mailed 14 April 2009). Furthermore, pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86) and in view of literature search for prior art; Claim 10 directed to a method of removing the reactivity of lipoarabinomannan to allow identification of the endotoxin by limulus reagent and Claim 13, drawn to a method of detecting an endotoxin-related disease are process Claims and are hereby rejoined and fully examined for patentability under 37 C.F.R. §1.104.

In accordance with the Official Gazette notice cited supra, process claims 1-5 and 17-19 as well as Kit/composition Claims 6-9, 14-16 and 20-23 respectively constituting inventive Groups A-B in the Office Action mailed 09/09/2009 and Groups II and IV (See Office Action mailed 14 April 2009), which do not depend from or otherwise include all the limitations of the method Claims 10-13, have NOT been rejoined. As a result of rejoinder *supra*, former groups C-D (See Office Action mailed 09/09/2009 and Interview Summary mailed 09/18/2009 are regrouped as invention of group C encompassing Claims 10-13. The remainder of the Claims (i.e., Claims 1-9, and 14-23) remain in their respective Groups as described in the Office Actions respectively mailed on 14 April and 09 September 2009.

Accordingly, Claims 1-9 and 14-23 are withdrawn from further consideration as being directed to a non-elected invention. See 37 C.F.R. §1.142(b) and M.P.E.P. §821.03.

8. Claims 10-13 are examined on merits.

Priority

9. Claim for foreign priority under 35 U.S.C. §119 (a-d) to PCT/JP04/19206 filed 12/22/2004 is hereby acknowledged.

Information Disclosure Statement

10. Information Disclosure Statements respectively filed 22 June 2006 and on 20 November 2007 are acknowledged, have been made of record, have been considered and duly initialed PTO FORM 1449 or equivalent are enclosed with the instant Office Action.

Objection to Specification

11. The specification is objected to because Line one of first page of specification, in its present form does not properly cite the application priority data. It is requested that the first line of the first page of the specification indicate that the instant application Claims priority to Japanese PCT.

Claim Rejections - 35 U.S.C. § 112

First Paragraph Rejections

12. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> ***The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact***

terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for a number of materials (See e.g., specification, Page 5, Lines 4-9) that are "referred to as binder of the present invention" (e.g., factor G activation inhibitor co-exiting with lipoarabinomannan (i.e., LAM), does not reasonably or clearly provide enablement for a step whereby the activity of said LAM in a sample containing said LAM is removed upon adding "limulus reagent" to said sample . Accordingly, the specification as currently presented does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with said Clams 10-13 especially in view of teachings of the prior art (See, Savedra, Jr, et al. 1996. Mycobacterial Lipoarabinomannan Recognition Requires a Receptor That Shares Components of the Endotoxin Signaling System. Journal of Immunology, Volume 157, Pages 2549-2554; NPL Reference 3 cited in Applicants' IDS filed 22 June 2006).

Claims 10-13 are drawn to a method to measure an endotoxin using a Limulus reagent in a LAM-containing sample comprising: **removing said LAM activity with a Limulus reagent** (Claim 11), wherein said LAM containing sample comprises a number of co-existing materials with said LAM in said sample (See instantly presented Claim 10, Lines 1-7). Said Limulus reagent is endotoxin-specific (Claim 12). Said method is applicable to detect an endotoxin-related disease (Claim 13).

From the record of the present written disclosure, the scope of the claimed invention recited in Claims 10-13 is not supported by the specification on record because in said specification, there is no evidence described to indicate that said LAM is actually removed with the addition of said endotoxin-specific Limulus Reagent, despite a description of materials coexisting with said LAM and also the description that said Limulus Reagent is endotoxin-specific (See, e.g., Specification, Page 5, Lines 4-24 and Page 4, Line 8).

A person of skill would not be able to practice the invention because undue experimentation will be required to obtain a method to remove said LAM applying said endotoxin-specific Limulus Reagent.

Undue experimentation will be required due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) as illustrated below.

A.Quantity of Necessary Experimentation

The specification at many places between page 3, Line 11 to Page 33, Line 18 recites the statement that LAM binds to a variety of materials (e.g., "anti-tuberculosis antibody, Concavalin A and the like" at page 33, Lines 10-11) or binding agents. At no place, however, there is a clear description or disclosure to evidence that the endotoxin-specific Limulus reagent in any shape or form removes activity of LAM. According to the pertinent art, even for the mycobacterial (i.e., tuberculosis bacterium) LAM a receptor common to both LPS and LAM is required. Said receptor is identified to be "Lipid IV_A and *Rhodobacter sphaeroides* Lipid A" and it is also recognized that a CD14-dependent LPS signal transducer" facilitates recognition of said LAM and recognition of endotoxin (i.e., LPS , viz. lipopolysaccharide) in the presence of a recombinant CD-14 (Abstract, Lines 13-17 in Savedra et al., 1996. Mycobacterial Lipoarabinomannan Recognition Requires a Receptor That Shares Components of the Endotoxin Signaling System. Journal of Immunology, Volume 157, Pages 2549-2554).

Thus, absent a clear description how the endotoxin –specific Limulus reagent removes or deactivates LAM in a sample containing said LAM, the currently presented specification does not support the invention Claimed in Claim 10. Since Claims 11-13 are dependent on Claim 10, the scope of the claimed invention recited in Claims 10-13 is not supported by the specification on record and a person of skill will have to perform a number of permutations and combinations to practice said claimed invention.

B.Limited Amount of Guidance

The specification as currently presented does not provide a clear-cut guidance to obtain the claimed invention, because said description of specification is limited to particularly pointing out that the LAM is inactivated rather than actually describing how said LAM is inactivated in the presence of said "endotoxin-specific Limulus reagent.

C.Limited Number of Working Examples in the Specification

The specification as currently presented does not provide any specific evidence to practice the claimed invention method to inactivate the Claimed LAM in a sample that contains said LAM. Accordingly, there is no evidence of measuring said endotoxin with the application of said Limulus reagent.

D.Nature of the invention

The currently presented specification does not delineate the inventive method to remove the activity of LAM in a LAM-containing sample with the application of an endotoxin-specific Limulus reagent as is currently described in the currently presented specification.

E.State of the Prior Art

The prior art description in the specification is adequate.

F.Relative Skill Level of those in the Art

At least a Bachelor Degree in, Bacteriology, Biochemical engineering, Biochemistry, Biology, Chemistry, Cytology, Enzymology, Immunology, Microbiology, Molecular biology, or Pharmacology.

G.Predictability or Unpredictability in the Art

Unless supported with illustrative experimental evidence, biological responses/ phenomenon are unpredictable. Thus, information obtained under one set of detrimental parameters may not be extrapolated for another set of parameters/environmental or specific conditions.

H.Breadth of the Claims

As noted above, in item A, there are a number of claim limitations (e.g., method to measure an endotoxin using a Limulus reagent in a LAM-containing sample comprising removing said LAM activity with a Limulus reagent, wherein said LAM containing sample comprises a number of co-existing materials with said LAM in said sample). Said Limitations are not clearly discernible absent clear description regarding instantly claimed removal of LAM in presence of endotoxin –specific Limulus reagent; especially when the pertinent art teaches that LAM interferes with the recognition/detection of an endotoxin with said Limulus reagent. Thus, the claimed invention is drawn upon claims that are not supported by the presently detailed specification.

35 U.S.C. §112 Second Paragraph Rejections

14. The following is a quotation of 35 U.S.C. §112, second paragraph:

> ***The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.***

15. Claim 13 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention because of range in range indefiniteness.

- The phrase, "comprising using" in Claim 13 renders said Claim incomprehensible, unclear, vague and therefore, indefinite. The phrase, " comprising using " in Claim 13 renders that claim indefinite because the word "using" is similar to word "use". Since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Conclusion

16. For the aforementioned reasons, no claims are allowed.

However, Claims 10-13 may be allowable upon resolution of the above-stated issues under 35 U.S.C. §112. Please note, upon resolution of above-stated issues under 35 U.S.C. §112, further searching and/or consideration may be required.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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10 February 2010

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